In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS No. 20-1092V UNPUBLISHED

PAULA JOHNSON,

Petitioner,

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SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: May 14, 2021

Special Processing Unit (SPU); Findings of Fact; Onset; Influenza (Flu) Vaccine; Guillain-Barré Syndrome (GBS)

Emily Beth Ashe, Anapol Weiss, Philadelphia, PA for Petitioner.

Naseem Kourosh, U.S. Department of Justice, Washington, DC, for respondent.

DECISION DISMISSING CASE¹

On August 28, 2020, Paula Johnson filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the "Vaccine Act"). Petitioner alleges that she suffered Guillain-Barré syndrome ("GBS") that was caused in fact by an influenza ("flu") vaccine received on September 11, 2018. Petition at 1. This case was assigned to the Special Processing Unit of the Office of Special Masters.

On April 2, 2021, Petitioner was ordered to show cause why this case should not be dismissed for insufficient proof. ECF No. 18. Petitioner filed a response on May 3, 2021. ECF No. 20. For the reasons discussed below, this claim is hereby **DISMISSED**.

¹ Although I have not formally designated this Decision for publication, I am required to post it on the United States Court of Federal Claims' website because it contains a reasoned explanation for the action in this case, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

I. Procedural History

This case was initiated on August 28, 2020. ECF No. 1. Petitioner filed medical records on October 8, 2020, and December 30, 2020, ultimately filing a statement of completion on December 30, 2020. ECF Nos. 7, 12, 13.

During an initial status conference, the staff attorney assigned to this case conveyed my initial thoughts regarding potential onset issues. In particular, the records indicated that Petitioner's first symptoms appeared no sooner than 92 days after her vaccination. ECF No. 18. This would put Petitioner's claim outside the longest time accepted for a causation-in-fact flu/GBS claim (and well outside the Table's timeframe of 3-42 days). For those reasons, I directed Petitioner to show cause why this claim should not be dismissed. ECF No. 18.

Petitioner filed her response to the order to show cause on May 3, 2021. ECF No. 20. Petitioner reported that there were no additional medical records, and respectfully requested a ruling on entitlement based on the existing filed records.

II. Factual Background

Petitioner received a flu vaccine on September 11, 2018. Ex. 1 at 4. On December 12, 2018, 92 days after her vaccination, she reported sudden onset numbness in her lower extremities. Ex. 2 at 1506, Ex. 14 (Affidavit of Paula Johnson) at 1. Petitioner specifically stated that she had experienced the numbness since 5 p.m. of that day. *Id.* Petitioner underwent a series of diagnostic scans and a lumbar puncture on December 13, 2018. *Id.* at 1514-1519, 1242. Despite normal protein levels obtained from a lumbar puncture (*id.* 1242 and 1300-1317), based on her presentation and neurological exam, Petitioner was found to possibly have GBS,³ and received five doses of IVIG. *Id.* at 1421-22. She showed some improvement, but was still "very symptomatic" after the IVIG treatment. *Id.* at 1423.

Petitioner was discharged to a rehabilitation facility on December 19, 2018, where she stayed until January 3, 2019. Ex. 2 at 695. Her diagnoses at discharge included GBS. *Id.* Petitioner treated symptoms such as incontinence, balance and gait problems, numbness, and weakness of her lower extremities in the following months, and was provided with a "cannot return to work" letter on March 26, 2019. Ex. 5. She continued to work with her treating physicians and physical therapists until at least February 20, 2020, when she was discharged from physical therapy and advised to continue with a home

2

³ Petitioner's differential diagnosis also included transverse myelitis. Ex. 2 at 1422.

exercise program. Ex. 6 at 15-18. Due to lingering symptoms, Petitioner continues to treat her urinary and neurological issues. *See* Petition at 12.

III. Authority

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding her claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id*.

To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. See Burns v. Sec'y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. See Cucuras v. Sec'y of Health & Human Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records testimony, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." Sanchez v. Sec'y of Health & Human Servs., No. 11–685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing Blutstein v. Sec'y of Health & Human Servs., No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,⁴ a petitioner must establish that she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, GBS is compensable if it manifests within 3-42 days (not less than three days and not more than 42 days) of the administration of an influenza vaccination. 42 C.F.R. § 100.3(a)(XIV)(D). (Further criteria for establishing a GBS Table

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⁴ In summary, a petitioner must establish that she received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of her injury for more than six months, died from her injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. See § 11(c)(1)(A)(B)(D)(E).

Injury case be found under the accompanying qualifications and aids to interpretation. 42 C.F.R. § 100.3(c)(15)). Any onset outside that timeframe prevents the matter from succeeding as a Table claim, although it can often still be maintained as a non-Table, causation-in-fact claim.

Cases alleging a Table GBS/flu vaccine claim are readily dismissed for failure to establish the proper onset. See, e.g., Randolph v. Sec'y of Health & Human Servs., No. 18-1231V, 2020 WL 542735, at *8 (Fed. Cl. Spec. Mstr. Jan. 2, 2020) (finding GBS onset at the earliest occurred 76 days post-vaccination, "well outside the 3-42-day window set by the Table for a flu-GBS claim"). Further, in adjudicating non-Table versions of such a claim, special masters have frequently noted that six to eight weeks is the longest medically acceptable timeframe for onset of GBS following a flu vaccine. See, e.g., Chinea v. Sec'y of Health & Human Servs., No. 15-095V, 2019 WL 1873322, at *33 (Fed. Cl. Mar. 15, 2019), mot. for review den'd, 144 Fed. Cl. 378 (2019) (finding that the onset of the petitioner's GBS occurred eleven to twelve weeks after her vaccination, well beyond the six- to eight-week medically appropriate timeframe for the occurrence of vaccine-induced GBS); Barone v. Sec'y of Health & Human Servs., No. 11-707V, 2014 WL 6834557, at *13 (Fed. Cl. Spec. Mstr. Nov. 12, 2014) (finding eight weeks (56 days) is the longest reasonable timeframe for a flu vaccine/GBS injury).

IV. Finding of Fact

I make these findings after a complete review of the record, including all medical records, affidavits, and all other additional evidence and filings from the parties.

Petitioner alleges that she suffered from GBS that was caused-in-fact by a flu vaccine administered on September 11, 2018. Petition at 2. She thus does not attempt to argue that her onset fell within the Table's 3-42 day timeframe, as the petition alleges that the onset of her symptoms occurred on December 12, 2018. *Id.* Petitioner's affidavit and contemporaneous medical records preponderantly establish that the initial symptoms occurred on December 12, 2018. Ex. 2 at 1506, Ex. 14 at 1. This puts the onset of Petitioner's GBS at 92 days after her vaccination.

Such facts not only put Petitioner's claim outside the 42-day limit for a viable Table flu-GBS claim, but outside the *longest time* accepted for a similar non-Table claim. See, e.g., Williams v. Sec'y of Health & Hum. Servs., No. 19-1177V, 2021 WL 815921, at *2 (Fed. Cl. Jan. 19, 2021) (onset of GBS over 100 days after a flu vaccine was fatal to even a non-Table claim); Chinea, 2019 WL 1873322 at *33; Barone, 2014 WL 6834557 at *13.

Despite ample opportunity, Petitioner has failed to show cause, or provide any argument or explanation in response to my Order to Show Cause, as to why her claim should not be dismissed. Accordingly, I find the onset of petitioner's GBS began on December 12, 2018. I also find that the present facts cannot support a causation-in-fact claim, since an onset of more than ten weeks has never been deemed medically acceptable. *Barone*, 2014 WL 6834557, at *13. Petitioner has not otherwise offered any evidence that would suggest this onset "yardstick" should not be followed in this case.

V. Conclusion

The evidentiary record does not support Petitioner's contention that the flu vaccine she received in September 2018 caused her GBS, because her onset cannot be demonstrated as medically acceptable under the third prong of the test set forth in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

Therefore I must **DISMISS** Petitioner's claim in its entirety. **The clerk shall enter** judgment accordingly.⁵

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran Chief Special Master

⁵ If Petitioner wishes to bring a civil action, he must file a notice of election rejecting the judgment pursuant to § 21(a) "not later than 90 days after the date of the court's final judgment."